



May 20, 2021

Cook, Inc.
Karen Bradburn
Senior Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47402

Re: K073627
Trade/Device Name: Flexor Evac Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY

Dear Karen Bradburn:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 4, 2008. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'Connell -S
Digitally signed by
Gregory W. O'Connell -S
Date: 2021.05.20
10:10:15 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 2008

Cook, Inc.
c/o Ms. Karen Bradburn
Senior Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

Re: K073627
Trade/Device Name: Flexor Evac Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (Two)
Product Code: DXE
Dated: December 21, 2007
Received: December 26, 2007

Dear Ms. Bradburn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K073627

Device Name: Flexor Evac Aspiration Catheter

Indications for Use: Intended for removal of fresh, soft thrombi/emboli from the peripheral arterial system.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana D. Williams
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073627

510(k) Summary**Submitted By:**

MAR - 4 2008

Karen Bradburn, RAC
Senior Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, PO Box 489
Bloomington, IN 47402
812-339-2235

Device:

Trade Name:	Flexor Evac Aspiration Catheter
Proposed Classification:	Catheter, Embolectomy DXE (21 CFR §870.5150)

Indications for Use:

Intended for removal of fresh, soft thrombi/emboli from the peripheral arterial system.

Predicate Devices:

The Flexor Evac Aspiration Catheter is similar in terms of intended use, principles of operation, materials of construction and technological characteristics to predicate devices reviewed as devices for removal of fresh, soft thrombi/emboli from the peripheral arterial system. These devices include the Export XT Catheter (K061958) and the Pronto V3 Extraction Catheter (K063371).

Device Description:

The Flexor Evac Aspiration Catheter is hydrophilically coated, Flexor® material with a radiopaque band. The device is supplied with a Tuohy-Borst side-arm adaptor, stopcock valve, rapid exchange dilator, and a 30 mL vacuum syringe. This device is available in various lengths and French sizes.

Substantial Equivalence:

The Flexor Evac Aspiration Catheter is similar to catheters in commercial distribution used for removal of fresh, soft thrombi/emboli from the artery system.

The similar indications for use, principles of operation, technological characteristics and performance testing results for the Flexor Evac Aspiration Catheter as compared to the predicate device supports a determination of substantial equivalency.

Test Data:

The Flexor Evac Aspiration Catheter was subjected to the following tests to assure reliable design and performance under specified testing parameters. These tests include:

1. Pressure Rating
2. Liquid Leakage
3. Tensile Strength
4. Device Performance – Animal Study
5. Biocompatibility

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as an aspiration catheter.